# Measuring Adherence of Tecfidera®

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## Background

Tecfidera® is the first twice daily oral disease-modifying treatment for MS. Twice daily dosing for chronic medications has been well-studied and adherence has been shown to be between 50-80% . Cognitive and mood disorders are well-documented barriers to adherence, both common in Multiple Sclerosis. A study of adherence to twice a day therapy for Multiple Sclerosis treatment is needed to examine barriers to adherence and patterns of administration. Information about the Tecfidera® adherence rate in a standard of care setting (not a clinical trial) will be useful for future studies that seek to test ways to improve adherence to Tecfidera®.

## MOA Picture

## Objectives

This is a 12-month, exploratory study measuring the adherence rate of twice-daily oral Tecfidera®. The primary objective is to measure the adherence rate at week 24. Secondary objectives will include the relationship between mood, quality of life and tolerability as related to adherence. Patterns of adherence rates over the duration of the study will also be analyzed.

## Methods

Adherence will be measured using the Medication Event Monitoring System (MEMS) 6 monitor with LCD Display through the medAmigo web platform, as well as through pill counts performed on a monthly basis at site visit, or via phone. Questionnaires measuring quality of life (QOL) and symptoms will include the Multiple Sclerosis International Quality of Life (MusiQoL), Fatigue Severity Score (FSS), Multiple Sclerosis Neuropsychological Screening Questionnaire (MSNQ), Tolerability and Treatment Satisfaction (TSQM) and Beck Depression Inventory (BDI) and will be administered at baseline, week 12, and week 24. We will analyze results and report a confidence interval. Secondary objectives will be analyzed to look for any correlations between responses on the collected questionnaires and adherence rates.

## Discussion

Emerging oral therapies for Multiple Sclerosis show promise for patient adherence. Much of the research on MS patient adherence has been for injectable style therapies. This study will provide information on barriers that MS patients may face with an oral therapy, which will most likely prove to be quite different from the injectables. Data from this study will be valuable in designing protocols to promote adherence for MS patients initiating therapy with oral disease modifying medications.